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510(k) Summary

Preparation Date: July 7, 2007

Applicant/Sponsor: Biomet Trauma (formerly known as EBI, L.P.)
100 Interpace Parkway
Parsippany, NJ 07054

Contact Person: Debra L. Bing
Director, Regulatory Affairs
Biomet Trauma
973-299-9300

Proprietary Name: Biomet® Vision® FootRing System

Common Name: External Fixation Device

Classification Name: Single/multiple component metallic bone fixation appliances and accessories, 21 CFR 888.3030, KTT

Legally Marketed Devices To Which Substantial Equivalence Is Claimed: EBI® DynaFix® Vision® FootPlate System, K052239 (Biomet Trauma), Sheffield Ring Fixator, K944092, K955848 and/or subsequent (Orthofix, Inc.)

Device Description: The Biomet® Vision® FootRing System is an external fixation device. The devices in this 510(k) are additional modular components to the predicate Biomet® Vision® FootRing System, which is based upon the FootRing component as the frame for a construct.

Intended Use: The Biomet® Vision® FootRing System is intended for use in the treatment of bone conditions including leg lengthening, osteotomies, arthrodesis, fracture fixation, and other bone conditions amenable to treatment by the use of the external fixation treatment modality.

Summary of Technologies: The intended use is identical to the predicate Biomet® Vision® FootRing System. The new modular components are geometrically similar or identical to components in the predicate device. The new components incorporate similar or identical connection mechanisms to the predicates. Finally the new components are made from the same materials and finishes, conforming to the same standards as the predicate device.

Non-Clinical Testing: Mechanical testing of the Biomet® Vision® FootRing System was conducted to verify the static and fatigue design specifications and to determine performance with respect to the predicate. Mechanical Testing was also conducted to verify static design specifications for new connection components. The test results were as expected and demonstrate that the FootRing System is functional within its intended use, conforms to its design specifications and is substantially equivalent to the predicate device in performance characteristics. The minor technological differences between the Biomet® Vision® FootRing System and its predicate devices raise no new issues of safety and effectiveness. Performance

data indicate that the Biomet® Vision® FootRing System is as safe and effective as the EBI® DynaFix® Vision® FootPlate System, K052239. Thus, the FootRing System is substantially equivalent.

Clinical Testing: None provided as a basis for substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Biomet Manufacturing Corp.
% Mr. Robert Friddle
Regulatory Specialist
P.O. Box 587
Warsaw, Indiana 46581-0587

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Re: K071395
Trade/Device Name: Vision® FootRing System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: KTT
Dated: May 18, 2007
Received: May 21, 2007

Dear Mr. Friddle:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Bucknp

for

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071395

Device Name: Biomet® Vision® FootRing System

Indications for Use:

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Prescription Use ___Yes___ AND/OR Over-The-Counter Use __NO__
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Bucelli

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K071395